IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan) Patent Litigation	C.A. No. 20-2930-RGA
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. ALKEM LABORATORIES LTD., AUROBINDO PHARMA USA INC., AUROBINDO PHARMA LTD., DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., HETERO USA INC., HETERO LABS LIMITED, HETERO LABS LIMITED UNIT III, LAURUS LABS LIMITED, LAURUS GENERICS INC., MACLEODS PHARMACEUTICALS LTD., MACLEODS PHARMA USA, INC., TORRENT PHARMA INC., TORRENT PHARMACEUTICALS LTD., Defendants.	C.A. No. 21-1330-RGA

MEMORANDUM OPINION

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September 27, 2022

ANDREWS, UNITED STATES DISTRICT JUDGE:

Before me are Plaintiff's motions to dismiss the declaratory judgment counterclaims against Plaintiff's U.S. Patents Nos. 9,517,226 ("'226 patent"), 9,937,143 ("'143 patent"), 11,135,192 ("'192 patent"), and 11,058,667 ("'667 patent") filed by Defendants Hetero USA Inc., Hetero Lab Limited, and Hetero Labs Limited Unit III ("Hetero"), and Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. ("Torrent"). (D.I. 37 (motion to dismiss Hetero's counterclaims), D.I. 40 (motion to dismiss Torrent's counterclaims)). I have considered the parties' briefing. (D.I. 38, 55, 60, 63 (briefing for Plaintiff's motion to dismiss Hetero's counterclaims), D.I. 41, 54, 58, 64 (briefing for Plaintiff's motion to dismiss Torrent's counterclaims)). For the reasons set forth below, Plaintiff's motions are GRANTED.

I. BACKGROUND

Plaintiff received notice that Hetero and Torrent had filed ANDA applications for generic versions of Novartis's Entresto product in September 2019. (D.I. 1 at ¶¶39, 73). Subsequently, Plaintiff sued Hetero and Torrent (in addition to other co-Defendants) alleging infringement of U.S. Patent No. 11,096,918 (the "'918 patent") in September 2021. (D.I. 1 at ¶1). In October 2021, Hetero and Torrent answered Plaintiff's Complaint, and included counterclaims seeking declaratory judgment that the '226, '143, '192, and '667 patents are invalid and/or not infringed. (D.I. 22, 24). Plaintiff listed those four patents in the Orange Book in connection with Entresto between March 2021 and October 2021. (D.I. 60-1, Ex. A). Thus, Hetero and Torrent had filed their ANDA applications before Novartis listed the four patents in the Orange Book.

Hetero and Torrent supplemented their ANDA applications to include statements pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) ("Section viii statements") for the '226, '143, and '192 patents. Those statements affirm that their ANDA products will omit from their labeling any methods of

use that infringe those patents. (D.I. 54-1, Ex. 1 (including Torrent's Section viii statement for the '226 and '143 patents), D.I. 55-1, Ex. 1 (including Hetero's Section viii statement for the '226 and '143 patents), D.I. 58 at 4 (confirming that "Torrent filed a section viii statement for the '226, '143, and '192 … patents"), D.I. 60 at 4 (confirming that "Hetero filed a section viii statement for the '226, '143, and '192 … patents")). Hetero and Torrent did not certify pursuant to 35 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") that the '226, '143, and '192 patents will not be infringed and/or are invalid. (D.I. 58 at 4, D.I. 60 at 4).

Plaintiff separately moved to dismiss Hetero's and Torrent's counterclaims pursuant to Rule 12(b)(1), Rule 12(b)(6), and 28 U.S.C. § 2201. The briefing on the two motions is substantively identical. Thus, for convenience, I will refer to Hetero and Torrent together as Defendant and only cite to Hetero's briefing.

After the briefing on the motions to dismiss, the Parties stipulated to the dismissal of the counterclaims against the '667 patent. (D.I. 75, 76). Thus, only the counterclaims as to the '226, '143, and '192 patents remain.

II. LEGAL STANDARD

A. Rule 12(b)(1)

Federal Rule of Civil Procedure 12(b)(1) permits the dismissal of a claim or an action for lack of subject matter jurisdiction. A Rule 12(b)(1) motion may be treated as either a facial or factual challenge to the court's subject matter jurisdiction. *See Davis v. Wells Fargo*, 824 F.3d 333, 346 (3d Cir. 2016). A facial attack contests the sufficiency of the pleadings, whereas a factual attack contests the sufficiency of jurisdictional facts. *See Lincoln Ben. Life Co. v. AEI Life, LLC*, 800 F.3d 99, 105 (3d Cir. 2015). When considering a facial attack, the court accepts the plaintiffs well-pleaded factual allegations as true and draws all reasonable inferences from those allegations

in the plaintiff's favor. *See In re Horizon Healthcare Servs. Inc. Data Breach Litig.*, 846 F.3d 625, 633 (3d Cir. 2017). The party asserting subject matter jurisdiction bears "the burden of proof that jurisdiction does in fact exist." *Mortenson v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1997).

In declaratory judgment actions, the plaintiff must show that "a case of actual controversy" exists to establish subject matter jurisdiction sufficient to maintain an action in federal court. 28 U.S.C. § 2201(a). The Supreme Court has held that a "case or controversy" exists when "the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). "The dispute must be definite and concrete, touching the legal relations of parties having adverse legal interests...." *Arris Grp., Inc. v. British Telecomm. PLC*, 639 F.3d 1368, 1373 (Fed. Cir. 2011) (cleaned up). A "subjective or speculative fear of future harm" does not suffice. *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1335 (Fed. Cir. 2008).

B. Rule 12(b)(6)

Rule 8 requires a complainant to provide "a short and plain statement of the claim showing that the pleader is entitled to relief...." Fed. R. Civ. P. 8(a)(2). Rule 12(b)(6) allows the accused party to bring a motion to dismiss the claim for failing to meet this standard. A Rule 12(b)(6) motion may be granted only if, accepting the well-pleaded allegations in the complaint as true and viewing them in the light most favorable to the complainant, a court concludes that those allegations "could not raise a claim of entitlement to relief." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007).

The factual allegations do not have to be detailed, but they must provide more than labels, conclusions, or a "formulaic recitation" of the claim elements. *Id.* at 555 ("Factual allegations must be enough to raise a right to relief above the speculative level ... on the assumption that all the allegations in the complaint are true (even if doubtful in fact)."). Moreover, there must be sufficient factual matter to state a facially plausible claim to relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The facial plausibility standard is satisfied when the complaint's factual content "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* ("Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." (cleaned up)).

III. DISCUSSION

Plaintiff argues that Defendant's declaratory judgment counterclaims against the '226, '143, and '192 patents should be dismissed because (1) they are barred by statute, (2) Defendant lacks standing to assert these counterclaims, and (3) the Court should exercise its discretion to dismiss them. (*See* D.I. 55-1).

The parties' arguments regarding whether Defendant's counterclaims are barred by statute and whether Defendant lacks standing are overlapping. I will address these arguments together.

Plaintiff argues, "[Defendant] is barred by statute from asserting declaratory judgment counterclaims against the '226, '143 [and] '192 … patents because [Defendant] has not served on Novartis any Paragraph IV notice letter for [those] patents" as is required by 21 U.S.C. § 355(j)(5)(C)(i) of the Hatch Waxman Act and 35 U.S.C. § 271(e)(5) of the Patent Act. (D.I. 55-1 at 5-7, 5). Specifically, Plaintiff explains that both 21 U.S.C. § 355(j)(5)(C)(i)(aa)-(bb) and 35 U.S.C. § 271(e)(5) restrict an ANDA applicant from filing a declaratory judgment action for a

patent unless the applicant filed a Paragraph IV certification for that patent and the patent owner was first given 45 days to bring an action for infringement. (D.I. 55-1 at 5-6 (citing *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1335 (Fed. Cir. 2007) (explaining that 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5) "work[] in conjunction"))).

Given that "a Paragraph IV certification is a statutory prerequisite to an ANDA applicant's claim for declaratory judgment relief under 21 U.S.C. § 355(j)(5)(C)(i) and/or 35 U.S.C. § 271(e)(5)," Plaintiff further argues that Defendant lacks standing to assert the counterclaims. (D.I. 55-1 at 11-13, 12). Plaintiff asserts, "Because [Defendant] has declined to submit a Paragraph IV certification for the '226, '143, and '192 … patents, and instead has chosen to submit Section viii statements for those patents, [Defendant] does not have standing to seek declaratory judgment under those statutes for those patents." (D.I. 55-1 at 11-13, 12 (citing *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1349 (Fed. Cir. 2007) (affirming the dismissal of an ANDA applicant's declaratory judgment counterclaims for lack of subject matter jurisdiction when the ANDA applicant failed to show a "substantial controversy [between the parties] of sufficient immediacy and reality to warrant the issuance of a declaratory judgment") (quoting *MedImmune*, 549 U.S. at 127))).

In response, Defendant argues that 21 U.S.C. § 355(j)(5)(C)(i) is inapplicable to its counterclaims because this statute applies only to patents "against which paragraph IV certifications have been filed" and that "have been submitted for listing in the Orange Book before the date on which the ANDA … was submitted." (D.I. 60 at 5-10, 5). Defendant asserts that 35 U.S.C. § 271(e)(5) "does not alter" its analysis of 21 U.S.C. § 355(j)(5)(C)(i) because "§ 271(e)(5) confirms the existence of, but does not limit, declaratory judgment jurisdiction." (D.I. 60 at 9-10).

Since 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5) do not apply, Defendant argues that, instead, "35 U.S.C. § 271(e)(2) creates jurisdiction for an ANDA filer's declaratory judgment action." (D.I. 60 at 7). Defendant suggests that 35 U.S.C. § 271(e)(2) "provides an affirmative basis for [Defendant's] counterclaims" because "the Federal Circuit has held that submission of an ANDA alone, not submission of a paragraph IV certification, creates justiciable controversy." (D.I. 60 at 5-6 (citing *Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1124 (Fed. Cir. 2018))). Defendant stresses that, according to the *Teva* decision, "jurisdiction is a two-way street" (D.I. 60 at 6), where "if [filing an ANDA] creates a justiciable controversy for one party, the same action should create a justiciable declaratory judgment controversy for the opposing party." *Teva*, 482 F.3d at 1342.

Defendant further asserts that its "section viii statements do not divest the Court of jurisdiction" because 35 U.S.C. § 271(e)(2) "provides [Defendant] the right to sue for declaratory judgment" irrespective of whether a Paragraph IV certification or Section viii statement was filed. (D.I. 60 at 14-15). Even so, given that a case of actual controversy must exist for this Court to have subject matter jurisdiction, Defendant emphasizes the uncertainty that the *GSK* decision, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021), caused for ANDA applicants relying on Section viii—namely, that a generic manufacturer could later be found liable for infringing methods of use that were omitted from their labels under Section viii. (D.I. 60 at 2-3, 15-18). Defendant claims, "Novartis refusing to grant a covenant not to sue … yet precluding [Defendant] from seeking certainty [through its declaratory judgment counterclaims] … confirms that there is a controversy of sufficient immediacy and reality to warrant declaratory judgment[.]" (*Id.* at 3; *see also id.* at 15-18, 17 ("But Novartis refuses to grant a covenant not to sue, so, given *GSK*, a present controversy exists."), 18 ("[I]n this post-*GSK* world, by refusing to grant a covenant

not to sue, yet attempting to avoid pre-launch litigation, Novartis would have its patents hang over [Defendant], with Novartis lying in wait for [Defendant] to launch, so Novartis can then potentially seek an injunction and damages when it hurts most.")).

I agree with Defendant that 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5) do not statutorily bar the declaratory judgment counterclaims and warrant dismissal under Rule 12(b)(6). Instead, these statutes are specific to situations where a Paragraph IV certification was filed. *See* 21 U.S.C. § 355(j)(5)(C)(i)(aa)-(bb) (stating that "no action may be brought under section 2201 of title 28 by an [ANDA applicant] for a declaratory judgment with respect to a patent which is subject of [a Paragraph IV certification] unless [(aa)] the 45-day period referenced to in [21 U.S.C. § 355(j)(5)(B)(iii)] has expired [and (bb)] neither the owner of such patent nor the [NDA holder] brought a civil action against the applicant for infringement of the patent before the expiration of such period"); 35 U.S.C. § 271(e)(5) ("Where a person has filed an [ANDA] application … that includes a [Paragraph IV certification], and neither the owner of the patent that is subject of the certification nor the [NDA holder] brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice … was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed."). These statutes also do not, however, provide a statutory basis for, or subject matter jurisdiction over, Defendant's counterclaims. *See also Teva*, 482 F.3d at 1338 ("The Declaratory Judgment Act and 35 U.S.C. § 271(e)(5) are examples of legislation that expand standing to constitutional limits and provide a way for plaintiffs to bring actions in federal court when they might otherwise be barred.").

In that vein, I disagree with Defendant that, instead, "35 U.S.C. § 271(e)(2) deems submission of an ANDA a technical act of infringement, thereby creating jurisdiction including declaratory judgment jurisdiction" over its counterclaims. (D.I. 60 at 2-3, 2). I find that 35 U.S.C. § 271(e)(2) does not provide this Court subject matter jurisdiction over Defendant's counterclaims and that the *Teva* decision should not be interpreted to suggest otherwise.

Thirty-five U.S.C. § 271(e)(2) provides this Court with subject matter jurisdiction over infringement claims filed by patent owners. *See* 35 U.S.C. § 271(e)(2) ("It shall be an act of infringement to submit (A) an [ANDA] application … for a drug claimed in a patent or the use of which is claimed in a patent…"). Particularly, for a patent owner, "the requirements for jurisdiction in the district courts are met once [the] patent owner alleges that another's filing of an ANDA infringes its patent under 35 U.S.C. § 271(e)(2)…." *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012).

It does not follow, however, that there is subject matter jurisdiction in this case over the counterclaims. Defendant argues that § 271(e)(2) provides a "two-way street" for declaratory judgment jurisdiction based on a statement from the *Teva* decision. (D.I. 60 at 6 (citing *Teva*, 482 F.3d at 1342 ("[I]f [submitting an ANDA] creates a justiciable controversy for one party, the same action should create a justiciable declaratory judgment controversy for the opposing party."))). I disagree with Defendant's interpretation. It ignores the statement's context. The cited language from *Teva* is limited to the context of an ANDA applicant that submitted a Paragraph IV certification. *See Teva*, 482 F.3d at 1342 (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (holding that 35 U.S.C. § 271(e)(2) creates "a highly artificial act of infringement that consists of submitting an ANDA ... containing the fourth type of certification")), 1345 (explaining that, when an ANDA applicant certified patents under Paragraph IV, they indefinitely "remain[]

subject to … infringement actions … under 35 U.S.C. § 271(e)(2)[,]" thus substantiating a "threat of protracted litigation [which] creates a present and real harm")). Indeed, the *Teva* decision states that whether an ANDA applicant relied on a Paragraph IV certification is "dispositive" in determining whether they have a "justiciable declaratory judgment controversy." *Id.* at 1344 ("A justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents. The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents…."); *see also id.* at 1335 (considering whether an ANDA filer's declaratory judgment actions brought "under 21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5)" should be dismissed).

On the other hand, for a declaratory judgment action brought by an ANDA applicant under 35 U.S.C. § 271(e)(5), "Congress explicitly extended federal court declaratory judgment jurisdiction under 28 U.S.C. § 2201 to ANDA paragraph IV disputes … and did so 'to the extent consistent with the Constitution.'" *Id.* at 1336 (quoting 35 U.S.C. § 271(e)(5)). There is an "actual controversy" in declaratory judgment actions under 35 U.S.C. § 271(e)(5) because, once an ANDA applicant files a Paragraph IV certification, they "remain[] under the threat of an infringement suit [once] the 45-day statutory window" passes. *Id.* at 1341.

An ANDA applicant that submits a Section viii statement does not create an "actual controversy" because there is no cause of action. A patent owner's infringement action under 35 U.S.C. § 271(e)(2)—while within the Court's jurisdiction independent of "the ultimate merits of the claim[]"—may be dismissed under Rule 12(b)(6) (as opposed to Rule 12(b)(1)) if the ANDA applicant submitted a Section viii statement. *See AstraZeneca*, 669 F.3d at 1377-80, 1380

("Because [ANDA filers] have submitted ANDAs seeking approval to market [a pharmaceutical] for uses that are not subject to [patent owner's] method of use patents, [patent owner] does not state a claim for infringement of these patents under § 271(e)(2)."). Indeed, "[§ 355(j)(2)(A)(viii) of the Hatch Waxman] Act allows generic manufacturers to limit the scope of regulatory approval they seek—and thereby forego Paragraph IV certification and a § 271(e)(2) infringement suit—by excluding patented indications from their ANDAs" using Section viii statements. *Id.* at 1379. Thus, an ANDA applicant that submits a Section viii statement for a patent does not face the imminent threat and actual controversy of an infringement action under 35 U.S.C. § 271(e)(2) for that patent.

Defendant asserts that the *GSK* decision creates an actual controversy for ANDA applicants that rely on Section viii statements because it raises the specter of later being found to infringe methods of use that they carved out. I do not agree. Defendant's concerns amount to no more than "subjective or speculative fear of future harm" that cannot justify subject matter jurisdiction. *Prasco*, 537 F.3d at 1335; *see also GlaxoSmithKline*, 7 F.4th at 1326 ("This narrow, case-specific review of substantial evidence does not upset the careful balance struck by the Hatch-Waxman Act regarding section viii carve-outs.").

In a recent supplemental filing, Defendant provides notice of a "citizen's petition" that Plaintiff filed with the FDA. (D.I. 110). In its citizen's petition, Plaintiff requests that the FDA "[r]efrain from approving any ANDA … until the expiration of the ['226, '143, and '192 patents] if that ANDA contains a section viii statement to these patents and seeks to omit the patent-protected use in [these] patents." (D.I. 110, Ex. 1 at 5). Plaintiff argues that the carve out to the Entresto label required to approve Defendant's ANDA would "not [be] consistent with FDA precedent." (*Id.*, Ex. 1 at 4). Considering Plaintiff's arguments in its citizen's petition, Defendant

asserts, "Novartis's challenge to generic companies' ability to rely on section viii statements with respect to the ['226, '143, and '192 patents] reinforces the existence of a dispute between Novartis and Torrent/Hetero regarding those patents that is appropriate for resolution on declaratory judgment." (*Id.* at 2). I disagree. Plaintiff's petition to the FDA, which to my knowledge has received no response, does not affect my analysis of whether this Court has subject matter jurisdiction over Defendant's declaratory judgment counterclaims.

For these reasons, I find that Defendant has not shown that this Court has subject matter jurisdiction over its declaratory judgment counterclaims against the '226, '143, and '192 patents. Thus, I will dismiss these counterclaims under Rule 12(b)(1).[1]

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[1] In the alternative, if there were subject matter jurisdiction, I would still dismiss the counterclaims.

Plaintiff argues, "The Court should exercise its discretion to dismiss [Defendant's] declaratory judgment counterclaims against the '226, '143, [and] '192 patents," because Defendant "jumped the gun and [has] prematurely filed declaratory judgment claims without complying with statutory requirements that provide [Plaintiff] advance notice of [Defendant's] substantive contentions, and the opportunity to sue [Defendant] first." (D.I. 55-1 at 7-11, 9 (citing *Paddock Lab'ys, Inc. v. Ethypharm S.A.*, 2011 WL 149860, at *4 (D.N.J. Jan. 18, 2011) (declining to exercise discretionary jurisdiction over an ANDA applicant's declaratory judgment action because "continuing [the] lawsuit [would be] contrary to the intent of the Hatch-Waxman Act"))).

Defendant responds, "[T]he Court should reject Novartis's attempt to transform its statutory-bar argument into a basis for the Court to exercise its discretion to deny declaratory judgment jurisdiction" because Defendant's counterclaims "accomplish exactly [the] purpose" of the Hatch-Waxman Act—"facilitat[ing] early resolution of patent disputes." (D.I. 60 at 2, 10-14).

"As long as the district court acts in accordance with the purposes of the Declaratory Judgment Act and the principles of sound judicial administration, it has broad discretion to refuse to entertain a declaratory judgment action." *Commc'ns Test Design, Inc. v. Contec, LLC*, 952 F.3d 1356, 1361-62 (Fed. Cir. 2020) (cleaned up). For the reasons provided above regarding the statutory requirements of 21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5) for declaratory judgment jurisdiction, were this Court to have subject matter jurisdiction, I would exercise my discretion not to entertain Defendant's declaratory judgment counterclaims. Given that Defendant did not submit Paragraph IV certifications for the '226, '143, and '192 patents, I do not believe that considering Defendant's declaratory judgment counterclaims would be an efficient use of judicial resources. Currently, Defendant is not at risk of Novartis filing a viable infringement action under 35 U.S.C. § 271(e)(2) for those patents. *See AstraZeneca*, 669 F.3d at 1380 (explaining that Section viii statements "allow[] generic manufacturers to limit the scope of regulatory approval they seek—and thereby forego Paragraph IV certification and a § 271(e)(2)

IV. CONCLUSION

For the reasons stated above, Plaintiff's motions to dismiss are GRANTED.

An appropriate order will issue.

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infringement suit—by excluding patented indications from their ANDAs"). Defendant asserts, "Novartis's approach to the section viii patents would permit a pre-launch suit by an NDA holder but foreclose any pre-launch declaratory action by an ANDA filer against any patents for which a section viii statement is submitted." (D.I. 60 at 13). But that is incorrect. Both parties are foreclosed from pre-launch suits against the patents for which Section viii statements were submitted.